REMARKS

Claims 1-105, 298 and 299 have been rejected under 35 U.S.C. § 112, ¶ 1, as failing to comply with the written description requirement. This rejection is respectfully traversed with respect to these claims as amended herein.

These claims have been amended merely to define the invention more specifically, and as amended are now submitted to define the invention with sufficient particularity and support in the written description to overcome the Examiner's rationale for this rejection and to be patentable now to the Applicants.

Rejected claims 2-4, 23, 24, 34-39, 55-57, 92-95 and 98 have been cancelled.

Claims 1, 9, and 43-47 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Hussein *et al.* this rejection is respectfully traversed with respect to these claims as amended herein.

These claims as amended herein now specifically recite "transluminally slidably positioning the ablative device through the at least one lumen of the flexible tubular member to locate the energy delivery portion at a first of a plurality of locations along the extended region at least partially within said distal end portion;

delivering ablative energy to said energy delivery portion to ablate said tissue region from within the tubular member along a length of the extended region about said first location;

transluminally slidably positioning the ablative device through the at least one lumen of the flexible tubular member to locate the energy delivery portion at a second of the plurality of locations along the extended region at least partially within said distal end portion and near the first location; and

delivering ablative energy to said energy delivery portion to ablate said tissue region from within the tubular member along another length of the extended region about said second location".

In addition, these dependent claims are further restricted by various recitations, for example, of an organ targeted for tissue ablation, and of patterns of multiple ablation targets.

These aspects of the claimed invention are not disclosed by Hussein *et al.* '892 which is not understood to position and reposition an ablative element within a flexible tubular member in a manner as claimed by applicants. At best, this reference merely discloses moving an entire assembly intra-vascularly to a fixed 'spot' location at which an occlusion exists, and does not disclose relative movement of an ablative element within a tubular member previously positioned in the body of a patient. Instead, a fixation of the assembly at a spot location in a vessel also establishes seals 34, 36 to prevent blood flow into the operative region. This reference is therefore deficient of disclosure of the procedural steps as clearly

recited in these amended claims which are therefore submitted to be patentably distinguishable over the cited art.

Rejected claim 99 has been cancelled.

Claims 1, 9-11, 43, 80, 82-86, 88-91, 106 and 107 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kesten *et al.* WO '469 in combination with Osypka '405. This rejection is respectfully traversed with respect to these claims as amended herein.

These claims now variously recite "transluminally slidably positioning the ablative device through the at least one lumen of the flexible tubular member to locate the energy delivery portion at a first of a plurality of locations along the extended region at least partially within said distal end portion;

delivering ablative energy to said energy delivery portion to ablate said tissue region from within the tubular member along a length of the extended region about said first location;

transluminally slidably positioning the ablative device through the at least one lumen of the flexible tubular member to locate the energy delivery portion at a second of the plurality of locations along the extended region at least partially within said distal end portion and near the first location; and

delivering ablative energy to said energy delivery portion to ablate said tissue region from within the tubular member along another length of the extended region about said second location".

These claims also recite "introducing the introducer sheath into an interior chamber of the heart;

introducing the guide sheath through the introducer sheath to extend the pre-shaped distal end portion of the guide sheath a short distance beyond the distal end of the introducer sheath in a direction which is sufficient to direct the distal end portion of the flexible tubular member towards the tissue region to be ablated; and

introducing the flexible tubular member through the guide catheter to position the distal end portion adjacent to or in contact with the tissue region to be ablated," and "transluminally slidably positioning an energy delivery portion of an ablative device through said flexible tubular member until said energy delivery portion is at least partially located within said distal end portion;

delivering ablative energy to said energy delivery portion to ablate tissue along said extended tissue region".

In addition, the dependent claims are further restricted by specific recitations, for example, of tissue of a type to be ablated, and of introduction or entry site into the heart.

These aspects of the claimed invention promote formation of a length of adjacent or contiguous locations of ablated tissue in a line, for example, about a vasculature opening within a chamber of the heart by delivery thereto of ablative energy from within the tubular member previously positioned about the targeted tissue.

These aspects of the claimed invention are not disclosed or even suggested in the cited references considered either alone or in the combination proposed by the Examiner. Specifically, Kesten et al. WO '469 is understood to disclose a spot cauterizer or tissue ablator that is manipulated to align an end of a delivery catheter (for laser energy) substantially normally to the surface to be impinged with tissue-ablating energy. At best, forming a region of ablated tissue (e.g., Figs, 22, 24, 26) requires re-orienting the tip of the delivery catheter to substantial perpendicularity with the impinged tissue surface. However, there is no disclosure or suggestion here of a flexible tubular body already positioned along an extended region of tissue to be ablated, and within which an ablation device is slidably positioned (i.e., separated from the target tissue by the tubular body), in a manner as claimed by applicants.

Nor does Osypka '405 disclose any procedure resembling applicants' claimed invention. At best, this reference appears to position an optical imaging device within a chamber of the heart, using balloons and frames of various shapes, to

illuminate and retrieve optical images of interior aspects of the heart. There is no suggestion here of positioning a tubular body along a region of tissue to be ablated for slidably guiding an ablative element therein to locations along the extended region of tissue adjacent the tubular guiding body, in a manner as claimed by applicants. Nor is there any suggestion found in the cited references for modifying the primary reference with apparatus of Osypka '405 in any way to yield applicants' claimed invention. At best, combining these references in a manner as proposed by the Examiner might yield a spot tissue ablator with an optical viewing channel, but not a sufficient *prima facie* basis from which obviousness can be properly determined. It is therefore respectfully submitted that amended claims 1, 9-11, 43, 80, 82-86, 88-91, 106 and 107 are now patentably distinguishable over the cited art.

Rejected claim 283 has been cancelled.

Claims 282, 284-297 and 300 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Cox *et al.* WO '187 in combination with Kesten *et a*l. WO '469. This rejection is respectfully traversed.

These claims as amended herein now variously recite "transluminally positioning the at least one ablation device within the at least one lumen of the flexible tubular member until the at least one ablation element is located at a first of the plurality of ablation positions along the length of the tubular member."

In addition, the dependent claims are further limited by such various recitations as encircling a pulmonary vein with the tubular member, and transluminally positioning an ablation device within the tubular member.

These aspects of the claimed invention are not shown or suggested by the references considered either alone or in the combination proposed by the Examiner. Specifically, Cox *et al.* WO '187 is understood to rely upon a cryogenic probe or probes of specific configuration for freezing to ablate tissue along the limited shapes of the probes, or within portions thereof as restricted by a thermal insulator containing an ablation-energy window. This reference is not understood to position a tubular member along the path for ablating tissue and then sliding an ablative device within the tubular member to multiple ablation sites along the path of the tubular member, in the manner as claimed by applicants.

Nor does Kesten *et al.* WO ' 469 disclose positioning a tubular member along the path for ablating tissue, and then sliding an ablative device within the tubular member to multiple ablation sites along the path of the tubular member, in the manner as claimed by applicants. At best, this reference proposes to align perpendicularly with the surface of tissue to be ablated. And, applicants are unable to find in the cited references any suggestion of positioning a tubular member along an ablative path for guiding the sliding movement of an ablative device along multiple positions within the tubular member, in the manner as claimed by

applicants. The deficient disclosures of these references, considered either alone or in combination, thus fail to establish even a *prima facie* basis from which a proper determination of obviousness under 35 U.S.C. § 103(a) can be made. It is therefore respectfully submitted that amended claims 282, 284-297 and 300 are now patentably distinguishable over the cited art.

Rejected claims 23, 24 and 92-95 have been cancelled.

Claims 1, 5-22, 40-48, 65-68, 104-107, 298 and 299 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Cox *et al.* WO '187 in combination with Osypka and Kesten *et al.* WO '469. This rejection is respectfully traversed with respect to these claims as amended herein.

Specifically, these claims variously recite "transluminally slidably positioning the ablative device through the at least one lumen of the flexible tubular member to locate the energy delivery portion at a first of a plurality of locations along the extended region at least partially within said distal end portion;

delivering ablative energy to said energy delivery portion to ablate said tissue region from within the tubular member along a length of the extended region about said first location;

transluminally slidably positioning the ablative device through the at least one lumen of the flexible tubular member to locate the energy delivery portion at

a second of the plurality of locations along the extended region at least partially within said distal end portion and near the first location; and

delivering ablative energy to said energy delivery portion to ablate said tissue region from within the tubular member along another length of the extended region about said second location".

In addition, the dependent claims are further restricted by such various specific recitations as respective ones of plural lesions overlap to form a continuous lesion, and plural lesions form substantially rectilinear or curvilinear patterns.

These aspects of the claimed invention are not shown or suggested by the references considered either alone or in the combination proposed by the Examiner. The deficient disclosures of Cox *et al.* WO '187 and Kesten WO '469 are discussed in the above Remarks, and Osypka '405 is considered to disclose a frame or loop structure and collapsible balloon for positioning a probe within the heart of a patient. There is thus no disclosure or hint of suggestion in any of these references of positioning a tubular member along the path for ablating tissue, and then positioning an ablative device at plural locations within the tubular member, in the manner as claimed by applicants. Thus, merely combining the references as proposed by the Examiner fails to yield or even suggest applicants' claimed invention. Claims 1, 5-22, 40-48, 65-68, 104-107, 298 and 299 are therefore submitted to be patentably distinguishable over the cited art.

Rejected claims 226-228 have been cancelled.

Claims 225, 229, 230, 234, 236 and 240-255 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Swanson *et al.* '012 in combination with Cox *et al.* WO '187 and Kesten *et al.* WO '469. This rejection is respectfully traversed.

These claims variously recite "introducing the ablation sheath through said incision and positioning the contact surface of the distal end portion of the sheath adjacent to or in contact with a tissue surface of the heart;

advancing said ablative device through the at least one lumen of said ablation sheath to locate the energy delivery portion of the device at least partially within said distal end portion of the sheath, said radially asymmetric geometry of said at least one lumen preventing rotation of said ablative device with respect to the ablation sheath during the step of advancing to orient the predetermined direction toward said tissue surface; and

applying tissue-ablating energy to said energy delivery portion for delivery through the sheath to form at least one lesion of ablated tissue along the tissue surface of the heart."

In addition, the dependent claims are further restricted by such various recitations as "forming at least one penetration in a wall of the heart into an interior chamber thereof; and introducing the ablation sheath through the penetration to

perform an ablative procedure within the internal chamber of the heart," and "repeating said forming at least one lesion at least one or more times to form two or more overlapping lesions on the heart," and various positions and penetrations of the ablation sheath with respect to heart tissue and chambers.

These aspects of the present invention are not shown or even suggested by the cited references considered either alone or in the combination proposed by the Examiner. Specifically, Swanson *et al.* '012 is understood to rely upon various configurations of porous electrodes for effecting ionic transport of a medium containing ions under control of applied electrical energy, and such apparatus and operation are understood to require the electrode to be outside a delivery sheath or cannula in order to contact tissue. The disclosure of this reference is submitted not to be illustrative or instructive of applicants' claimed invention, and the deficiencies of disclosures of Cox *et al.* WO '187 and Kesten *et al.* WO '469 are discussed in the above Remarks. Nor is there any suggestion in the cited references for assembling elements of such diverse arts to operate in accordance with the procedures as claimed by applicants. It is therefore respectfully submitted that claims 225, 229, 230, 234; 236 and 240-255 as variously amended herein are now patentably distinguishable over the cited art.

Rejected claims 92-94 have been cancelled.

Claims 25-33, 49-54, 58-64, 69-79, 81, 86, 87, 96 and 97 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hussein et al. '892 or Cox *et al.* WO '187 in combination with Osypka '405 and Kesten *et al.* WO '469. This rejection is respectfully traversed.

These claims are amended herein now variously recite "transluminally slidably positioning the ablative device through the at least one lumen of the flexible tubular member to locate the energy delivery portion at a first of a plurality of locations along the extended region at least partially within said distal end portion;

delivering ablative energy to said energy delivery portion to ablate said tissue region from within the tubular member along a length of the extended region about said first location;

transluminally slidably positioning the ablative device through the at least one lumen of the flexible tubular member to locate the energy delivery portion at a second of the plurality of locations along the extended region at least partially within said distal end portion and near the first location; and

delivering ablative energy to said energy delivery portion to ablate said tissue region from within the tubular member along another length of the extended region about said second location."

In addition, the dependent claims are further limited by such various recitations of ablative devices for delivering various forms of tissue-ablating energy from within a tubular member, and of shields and keying assemblies for directing a majority of ablation energy in a selected direction.

These aspects of the claimed invention are not disclosed or even suggested by the cited references considered either alone or in the combination proposed by the Examiner. Specifically, Hussein *et al.* '892 is understood to disclose moving an entire assembly intravascularly to a fixed 'spot' location at which an occlusion exists, and does not disclose relative movement of an ablative device along and within a tubular member that is disposed along the path for ablating tissue, in a manner as claimed by applicants. And, the deficiencies of disclosure contained in Cox *et al.* WO '187, as discussed in the above Remarks, fail to overcome the deficiency of Hussein *et al.* '892. Thus, merely combining the deficient disclosures of Osypka '405 and Kesten WO '469, as discussed in the above Remarks fails to establish even a *prima facie* basis from which a proper determination of obviousness under 35 U.S.C. § 103(a) can be made. Nor is there any hint or suggestion, or even any motivation, found in the cited art for combining 3 or 4 references in the manner as proposed by the Examiner. It is therefore respectfully submitted that claims 25-33, 49-54, 58-64, 69-79, 81, 86, 87, 96 and 97 as amended herein are now patentably distinguishable over the cited art.

Claims 225, 229, 232, 235, 238 and 239 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Swanson *et al.* '012 in combination with Cox *et al.* WO '187 and Kesten *et al.* WO '469. This rejection is respectfully traversed.

These claims specifically recite "introducing the ablation sheath through said incision and positioning the contact surface of the distal end portion of the sheath adjacent to or in contact with a tissue surface of the heart;

advancing said ablative device through the at least one lumen of said ablation sheath to locate the energy delivery portion of the device at least partially within said distal end portion of the sheath, said radially asymmetric geometry of said at least one lumen preventing rotation of said ablative device with respect to the ablation sheath during the step of advancing to orient the predetermined direction toward said tissue surface; and

applying tissue-ablating energy to said energy delivery portion for delivery through the sheath to form at least one lesion of ablated tissue along the tissue surface of the heart."

The dependent claims are further restricted by such specific limitations as "forming at least one penetration in a wall of the heart into an interior chamber thereof; and introducing the ablation sheath through the penetration to perform an ablative procedure within the internal chamber of the heart." These claims also

variously recite "forming at least one penetration in a wall of the heart is performed using a cutting member on a distal end of the ablation sheath," and "performing at least one portion of a coronary artery bypass graft procedure prior to or after said formation of at least one lesion."

These aspects of the claimed invention are not disclosed or even suggested by the cited references considered either alone or in any combination, for example, as proposed by the Examiner.

For example, Swanson et al. '012 is directed to porous electrodes for transporting to tissue a material containing ions, under electrical control. The deficiencies of disclosure of this reference are discussed in the above Remarks and are not remedied by the deficient disclosures of Cox *et al.* WO '187 or Kesten *et al.* WO '469, also discussed in the above Remarks. Thus, although the cited references may disclose treatment of heart tissue around the pulmonary veins with various energies of the type enumerated by the Examiner, the disclosures of these references are nevertheless deficient and insufficient to establish a *prima facie* basis including the recited procedural step from which a proper determination of obviousness can be made. It is therefore respectfully submitted that claims 225, 229, 232, 235, 238 and 239 as amended herein are now patentably distinguishable over the cited art.

Reconsideration and allowance of all pending claims are solicited.

Respectfully submitted,
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